

Application No.: 10/802,395
Filing Date: March 17, 2004

REMARKS

Claims 1-41, 54-61, 63, 68, and 74 were pending, Claims 42, 62, and 64-47 having been withdrawn. With the present Response, the Applicants amend Claims 1, 36, 54, 61 and 74, and add Claim 81; therefore, Claims 1-41, 54-61, 63, 68, 74, and 81 remain pending for consideration.

Although the Applicants do not acquiesce to the standing rejections, the Applicants have amended the claims in order to better clarify the claim language and to expedite prosecution. The Applicants reserve the right to prosecute previous versions of the amended claims in one or more future applications.

Claim Rejections under 35 U.S.C. §103

Claims 1-4, 20, 23-39, 54-61, 63 and 74 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,120,539 to Eldridge, et al. in view of U.S. Patent No. 5,879,366 to Shaw, et al. Claims 5-19, 21, 22, 40, and 41 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Eldridge in view of Shaw and further in view of International Publication No. WO 96/03091 to Notaras, et al. The Applicants respectfully traverse the rejection, as the applied art fails to teach or suggest all of the claim language or otherwise render the claims obvious.

Claims 1-35

Claim 1 has been amended to recite (emphasis added):

1. A biocompatible laminate fabric comprising:
a porous first membrane layer;
a porous second membrane layer; and
an open mesh bonding layer between the first and second membrane layers;
wherein the bonding layer holds the first and second membrane layers together by extending into one or more pores of each membrane layer; and
wherein open surface areas of the first and second membrane layers are configured to permit tissue ingrowth through the first and second membrane layers and across a surface of at least one of the first and second membrane layers.

Support for the foregoing amendment may be found throughout the original patent application's specification. For example, paragraph [0035] of the application's publication

provides, "the composite membrane open surface area permits tissue ingrowth through the composite membrane and across at least one of the first and second membranes."

The Applicants respectfully traverse the claim rejection, as the applied art fails to teach, suggest, or otherwise render obvious, all of the claim language. In addition, at least the Eldridge reference teaches away from the Eldridge-Shaw combination, as applied in the outstanding Office Action.

Neither Eldridge nor Shaw, alone or combined, teach or suggest at least open surface areas of first and second membrane layers that are configured to permit tissue ingrowth *through* the first *and* second membrane layers *and across* a surface of at least one of the first and second membrane layers.

In addition, Eldridge actually teaches away from tissue ingrowth through first and second membrane layers. For example, Eldridge teaches the use of "an adhesion resistance barrier" (Eldridge Abstract). Eldridge's barrier actually *discourages tissue ingrowth* and seeks to prevent tissue ingrowth through his composite lamination. Eldridge, column 3, lines 65-column 4, line 1 ("The barrier sheet may be formed of expanded polytetrafluoroethylene (ePTFE) having a fine pore size that discourages tissue ingrowth and viscera adhesion."). It would therefore contradict Eldridge's purpose to combine the applied art as proposed in the Office Action.

Indeed, at column 1, lines 46-52 Eldridge explains that his repair fabric includes:

a first sheet of porous and tissue infiltratable material, an adhesion resistant, microporous barrier sheet for isolating the first sheet from sensitive tissue and organs after implantation, and a second sheet that is united with the porous and tissue infiltratable first sheet and which is also fused to the barrier sheet to form a laminate composite construction.

However, Eldridge explains that during lamination the second sheet is melted such that it "flows into the microporous structure of the adhesion resistant covering, encapsulating the void network of the barrier upon solidification" Therefore, Eldridge's barrier sheet actually prevents tissue ingrowth through both sheets of his composite lamination, and across at least one of the sheet surfaces.

Shaw similarly fails to teach or suggest tissue ingrowth at all, let alone through first and second membrane layers and across a surface of at least one of the first and second membrane layers.

For at least these reasons, Claim 1 distinguishes over the applied art. Claims 2-35 depend from Claim 1 and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 2-35 distinguish over the applied art for the unique combinations of features recited in those claims.

Claims 36-41

Claim 36 has been amended to recite (emphasis added):

36. An implantable medical device comprising a biocompatible laminate fabric and a support structure, wherein the biocompatible laminate fabric comprises:

- a porous first membrane layer;
- a porous second membrane layer; and
- an open mesh bonding layer between the first and second membrane layers;

wherein the bonding layer holds the first and second membrane layers together by extending into one or more pores of each membrane layer; and

wherein open surface areas of the first and second membrane layers are configured to permit tissue ingrowth through the first and second membrane layers and across a surface of at least one of the first and second membrane layers.

Claim 36 distinguishes over the applied art for substantially the same reasons discussed above with respect to Claim 1. Claims 37-41 depend from Claim 36 and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 37-41 distinguish over the applied art for the unique combinations of features recited in those claims.

Claims 54-60

Claim 54 has been amended to recite (emphasis added):

54. A composite membrane suitable for use as a medical device lamination, comprising:

- a first membrane, having first membrane pores;
- a second membrane, having second membrane pores; and
- a mesh bonding layer, having a bonding layer open surface area and bonding layer pores, wherein the bonding layer at least partially extends into membrane pores of the first membrane and second membrane to form a composite membrane, wherein the composite membrane has a *composite membrane open surface area* in the range between about 10% and about 50%, and *wherein the composite membrane open surface area is configured to permit tissue ingrowth through the first and second membrane layers and across a surface of at least one of the first and second membrane layers.*

Claim 54 distinguishes over the applied art for substantially the same reasons discussed above with respect to Claim 1. In addition, Claim 54 distinguishes over the applied art because the applied art fails to teach or suggest a *composite membrane* having an *open surface area* in the range between about 10% and about 50%. Indeed, the Applicants explain, “The open surface area is the percentage of the layer’s or membrane’s area *that is open to both sides*.” See paragraph [0089] of the present application’s publication (emphasis added). In contrast, the applied art is silent as to any value of a *composite membrane* open surface area.

Instead, Eldridge suggests that his composite lamination does not have any open surface area at all. For example, at column 1, lines 53-58 Eldridge explains (emphasis added), “a surface portion of the . . . second sheet *melts* during lamination *and flows into the microporous structure of the adhesion resistant covering, encapsulating the void network* of the barrier upon solidification to form a strong mechanical fixation between the two materials.” Eldridge explains that during lamination, a surface portion of his second sheet melts and flows into the pores of his covering. By filling the pores in his covering, Eldridge suggests that his laminated fabric does not include an open surface area, such as a composite membrane area that is open to both sides. Therefore, Claim 54 distinguishes over the applied art for at least this reason as well.

Claims 55-60 depend from Claim 54 and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 55-60 distinguish over the applied art for the unique combinations of features recited in those claims.

Claims 61, 63, and 68

Claim 61 has been amended to recite (emphasis added):

61. A laminated medical device, suitable for implantation within a medical patient, comprising:

- a frame;
- a first membrane, having first membrane pores;
- a second membrane, having second membrane pores; and
- a mesh bonding layer, having a bonding layer open surface area and bonding layer pores, wherein the bonding layer at least partially extends into membrane pores of the first membrane and second membrane to form a composite membrane, wherein the composite membrane has a *composite membrane open surface area* in the range between about 10% and about 50%, and *wherein the composite membrane open surface area is configured to permit tissue ingrowth through the first and second membrane layers and across a surface of at least one of the first and second membrane layers*.

Claim 61 distinguishes over the applied art for substantially the same reasons discussed above with respect to Claims 1 and 54. Claims 63 and 68 depend from Claim 61 and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 63 and 68 distinguish over the applied art for the unique combinations of features recited in those claims.

Claim 74

Claim 74 has been amended to recite (emphasis added):

74. A stent, suitable for implantation within a medical patient, comprising:

- a frame configured for use as a stent;
- a first membrane, having first membrane pores;
- a second membrane, having second membrane pores; and
- a mesh bonding layer, having a bonding layer open surface area and bonding layer pores, wherein the bonding layer at least partially extends into membrane pores of the first membrane and second membrane to form a composite membrane, and *wherein the stent has a first end and a second end and an elongate generally cylindrical body extending therebetween, wherein the first end diameter is smaller than the cylindrical body length, and wherein the stent is adjustable from a first configuration having a reduced diameter to a second configuration having an expanded diameter, the stent forming a conduit in the second configuration.*

Claim 74 distinguishes over the applied art at least because the applied art fails to teach or suggest a stent having a first end and a second end and an elongate generally cylindrical body extending therebetween, wherein the first end diameter is smaller than the cylindrical body length, and wherein the stent is adjustable from a first configuration having a reduced diameter to a second configuration having an expanded diameter, the stent forming a conduit in the second configuration.

For example, the applied art clearly fails to teach or suggest any form of stent, as that term is well understood in the art, let alone one having a generally cylindrical body, or one in which a first end diameter is smaller than the body length.

The Office Action explains that it “relied upon Shaw for teaching a structure that collapses in order to be put in place for repair and then expands when in place.” Office Action, p. 13. However, even if true, Shaw’s reinforcement wire is not a stent, and certainly not a stent having reduced and expanded diameter configurations. Indeed, Shaw’s reinforcement wires are

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merely folded over to facilitate introduction into the desired bodily location (see Shaw, Figures 6A-6C and 7A-7C).

The Office Action quotes Webster's dictionary for a definition of a stent; however, the Office Action's reading of Shaw's wire as a stent fails to correspond to the language of the quoted definition. Indeed, although the Office Action's quoted definition of a stent is "a short narrow metal or plastic tube often in the form of a mesh that is inserted into the lumen of an anatomical vessel . . . especially to keep a previously blocked passageway open", the Office Action merely states, "Shaw teaches a wire that is equated with the claimed frame. Shaw teaches a circular structure which would have a diameter and therefore Shaw teaches this limitation." Office Action, p. 14. Nowhere does Shaw or any of the applied art suggest that Shaw's wire support is a tube, in the form of a mesh, and/or to be inserted into the lumen of an anatomical vessel especially to keep a previously blocked passageway open.

Furthermore, the Applicants do not necessarily agree with or adopt the definition of a stent provided by the Office Action. Instead, the Applicants merely provide the quoted language to demonstrate the inconsistencies and failings of the Office Action rejection.

Therefore, for at least these reasons, Claim 74 distinguishes over the applied art.

New Claim 81

Claim 81 depends from Claim 74 and therefore distinguishes over the applied art for at least the same reasons discussed above. In addition, Claim 81 distinguishes over the applied art for the unique combinations of features recited in that claim. For example, Claim 81 includes similar language to the newly added language of Claims 1, 36, 54, and 61. Therefore, Claim 81 also distinguishes over the applied art for at least the same reasons discussed above with respect to those claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this

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application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of the foregoing amendments and remarks, the Applicants submit that this application is in condition for allowance and such action is respectfully requested. If any issues remain or require further clarification the Examiner is respectfully requested to call the Applicants' counsel at the number indicated below in order to resolve such issues promptly. Furthermore, by focusing on specific claims and claim limitations in the discussion above, the Applicants do not intend to imply that other claim limitations are disclosed or suggested by the art of record. In addition, although the Applicants have addressed only the rejections of the independent claims, the Applicants do not acquiesce or agree with many, if not all, of the dependent claim rejections. For example, the Applicants do not necessarily agree with any of the Office Action's characterizations of that which would be "inherent" to any of the Applicants' claimed features.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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